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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/759,484	01/12/2001	Mauro Perritti	1493-131 US	1744

7590 04/28/2004

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EXAMINER	
CARLSON, KAREN C	
ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/759,484	PERRITTI ET AL.	
	Examiner	Art Unit	
	Karen Cochrane Carlson, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *7 and 8* is/are allowed.

6)☐ Claim(s) *1-6 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/4/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

This Office Action is in response to the paper filed March 4, 2004.

Claims 1-11 are pending and are currently under examination.

Priority is to filing date of PCT/GB98/02391, July 24, 1998.

Withdrawal of Objections and Rejections

The objection to the disclosure because the claims do not identify the amino acid sequences with sequence identification numbers is withdrawn.

The rejection of Claims 6- 8 under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101 is withdrawn.

The rejection of Claims 7 and 8 under 35 U.S.C. 112, second paragraph, is withdrawn.

Maintenance of Rejections

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6 and 10-11 are again rejected under 35 U.S.C. 102(b) as being anticipated by Seemann et al. (1996; Molecular Biology of the Cell 7:1359-1374). In Fig. 2, Seemann et al. teach pig, cow, and rat annexin 1 polypeptide comprising AMVSE and not EQEYVQTV (Claims 1, 2, 5). Pig and cow annexin 1 comprise the sequence AMVSEFLKQAW (Claim 3). Mice were immunized

with annexin 1 from bovine (cow; page 1362, col. 2, para. 2); therefore, cow annexin 1 was placed a in pharmaceutical composition (Claim 4) and used to manufacture a medicament (Claim 6). New Claims 10-11 are included in this rejection because the compound is the same, and thus effective to treat or prevent inflammation and prevent leukocyte migration.

Claim 1-6 and 10-11 are again rejected under 35 U.S.C. 102(b) as being anticipated by Croxtall et al. 1993. Croxtall et al. teach N-terminal fragments of lipocortin 1 consisting of MAMVSEFLKQAW (Claims 1-3, 5). The fragment was placed in DMEM/F-12 medium and applied to A549 cells; therefore, the fragment was placed into a pharmaceutical composition (Claim 4) and manufactured into a medicament (Claim 6). New Claims 10-11 are included in this rejection because the compound is the same, and thus effective to treat or prevent inflammation and prevent leukocyte migration.

Applicants argue both art rejections together. Applicants urge that they have found that amino acids 2-6 of LC-1 is the pharmaceuticallly active portion of LC-1 and therefore the references do not anticipate the claims. The claims are drafter as "comprising" AMSVE, and thus the polypeptides taught in Seemann et al. and in Croxtall et al. anticipate the claims as written.

Applicants urge that neither Seemann et al. or Cróxtall et al. teach the medical use of annexin 1 or LC-1. Indeed, Claims 7 and 8, drawn to a method for treating inflammation, are allowable – see below.

Applicants urge that Croxtall et al. do not teach the inhibition of A549 cell growth. by the 1-12 peptide. In response, Applicants are urged to review Figure 4, wherein EGF stimulation of A549 cell proliferation is inhibited by peptides 1-12. In Figure 5, EGF stimulated release of PGE2 by the A59 cells was significantly inhibited by peptides 1-12. Thus, this argument is not persuasive.

Applicants argue that a later published article of Croxtall et al. (1998) that LC-1 peotide 1-12 did not inhibit PGE2 release in response to EGF. The Examiner cannot comment about the conflicting results by the same lead author. But, again, in the 1993 reference teaches that EGF stimulated release of PGE2 by the A59 cells was significantly inhibited by peptides 1-12.

Applicants urge that Seemann et al. teaches away from the 1-12 peptide because peptides in which the 13 N-terminal amino acids did not alter intracellular distribution, while those having a the 26 N-terminal amino acids deleted resulted in altered intracellular distribution. It is not clear what this observation has to do with the claimed invention, that is, this passage does not discuss the activity of annexin 1.

New Objections and Rejections

The disclosure is objected to because of the following informalities: The newly presented abstract on a separate sheet is required.

Appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 has been amended to refer to an "effective amount" of the compound of Claim 1. It is not clear what the limitation is, meaning, is the compound in a single dose form?

It appears that Applicants intend Claim 5 to read: A pharmaceutical composition of Claim 1, wherein said compound is in said composition in an effective amount to...

Claims 7 and 8 are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Karen Cochrane Carlson PhD

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER